UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

RICHARD K. MCINTIRE,

Plaintiff,

v.

Case No. 2:16-cv-185
CHIEF JUDGE EDMUND A. SARGUS, JR.
Magistrate Judge Terence P. Kemp

BAXTER INTERNATIONAL INC., et al.,

Defendants.

OPINION AND ORDER

This matter is before the Court for consideration of Defendant Baxter Healthcare Corporation's Motion to Strike and Dismiss Plaintiff's Fifth Cause of Action for Punitive Damages [ECF No. 16]. For the following reasons, Defendant's Motion is **DENIED**.

I.

Plaintiff Richard McIntire ("McIntire") alleges that his wife, Sandra McIntire ("Mrs. McIntire"), used a faulty dialysis product manufactured by Defendant Baxter Healthcare Corporation ("Baxter")—the Baxter MiniCap ("MiniCap"). (Compl. ¶¶ 14–15, 28–35 [ECF No. 1].)[1] "The Minicap is a plastic cap containing a povidone-iodine soaked sponge, designed to isolate the connector of the solution transfer set used during peritoneal dialysis." (*Id.* ¶ 17.) Mrs. McIntire—who was undergoing home peritoneal dialysis as a result of her end-stage renal disease—placed an order with Baxter on August 14, 2014, for 60 MiniCaps. (*Id.* ¶¶ 31–32.) The MiniCaps she received were from Lot # GD897157. (*Id.* ¶ 33.) Mrs. McIntire began using them. (*Id.* ¶ 35.)

[1] McIntire initially sued both Baxter Healthcare Corporation and Baxter International, Inc. (Compl. at 1.) McIntire has since voluntarily dismissed Baxter International, Inc. (McIntire Notice of Dismissal at 1 [ECF No. 6].)

Mrs. McIntire was hospitalized numerous times from November 24, 2014, through her death on January 18, 2015. (Compl. ¶ 38.) On December 16, 2014, during one of those hospital visits, the hospital staff suspected that Mrs. McIntire might have bacterial peritonitis; her peritoneal dialysis was the suspected cause. (*Id.* ¶ 42.) Following additional observations and tests, Mrs. McIntire was diagnosed on January 8, 2015, with peritonitis. (*See id.* ¶¶ 43–54.) Peritonitis, McIntire explains, is "an inflammation of the membrane lining the abdominal wall and covering the abdominal organs." (*Id.* ¶ 18.) It "is caused by an infection from bacteria or fungi" and "can rapidly spread into the blood (sepsis), and to other organs and can lead to a severe life-threatening infection throughout the entire body, as well as death." (*Id.*) Mrs. McIntire was also suffering from acute respiratory failure, chronic obstructive lung disease, end stage renal disease, acute non ST segment elevation myocardial infarction, atrial fibrillation, diabetes mellitus type 2, hypertension, obstructive sleep apnea, anemia due to ESRD, and dysphagia. (*Id.* ¶ 54.) On January 18, 2015, Mrs. McIntire was admitted to the hospital for respiratory distress; while there, she went into cardiac arrest and could not be revived. (*Id.* ¶ 56.)

On January 6, 2015, Baxter had sent peritoneal dialysis providers an "Important Product Information" letter warning of the danger associated with particular MiniCap lots. (Compl. ¶ 19.) The letter indicated that Baxter had received complaints of the MiniCaps' defective condition and that the defective MiniCaps could increase the risk of peritonitis. (*Id.* ¶ 20; Jan. 6, 2015 Ltr. at PageID 23 [ECF No. 1-3].) Baxter sent a similar warning letter to peritoneal dialysis patients on January 12, 2015. (Jan. 12, 2015 Ltr. at PageID 26–28 [ECF No. 1-3].)

On January 27, 2015, Baxter sent an "Urgent Product Recall" letter addressed to Mrs. McIntire. (Compl. ¶ 21; Jan. 27, 2015 Ltr. at PageID 31–32 [ECF No. 1-4].) The letter indicated that Baxter had received complaints that certain lots of MiniCaps were defective. (Compl. ¶ 21.)

Mrs. McIntire had received MiniCaps from one of the lots being recalled: Lot # GD897157. (*Id.* ¶¶ 22, 24.) The sponges of the defective MiniCaps, the letter explained, were separating from the caps. (*Id.* ¶ 21.) Baxter again warned that the MiniCaps' defects could increase the risk of peritonitis. (*Id.*) The United States Food and Drug Administration ("FDA") issued a Class 2 Recall of the defective MiniCap lots on March 13, 2015. (*Id.* ¶ 25.)

Mrs. McIntire never saw or read the Urgent Product Recall letter or the FDA Class 2 Recall notice. (Compl. ¶ 59.) They were sent after her death on January 18, 2015. (*Id.*)

McIntire alleges that the defective MiniCaps caused his wife to develop peritonitis, which, in turn, caused her death. (Compl. ¶ 58.) McIntire brings five causes of action against Baxter: (1) Strict Products Liability—Manufacturing Defect; (2) Strict Products Liability—Defective Due to Inadequate Warning; (3) Wrongful Death; (4) Survivorship; and (5) Punitive Damages. (*Id.* ¶¶ 62–91.)

Baxter now moves to strike and dismiss McIntire's punitive damages claim.

II.

As an initial matter, although Baxter ostensibly moves to strike and dismiss McIntire's punitive damages claim, Baxter's Motion never addresses the request to strike. (*See generally* Baxter Mot. to Dismiss [ECF No. 16].) Baxter's motion to strike the punitive damages claim is, accordingly, denied, and the Court will focus on Baxter's motion to dismiss.

Federal Rule of Civil Procedure 12(b)(6) provides for dismissal of actions that fail to state a claim upon which relief may be granted. Fed. R. Civ. P. 12(b)(6). Such an action will be dismissed where "there is no law to support the claims made" or where "the facts alleged are insufficient to state a claim." *Stew Farm, Ltd. v. Natural Res. Conservation Serv.*, No. 2:12-cv-299, 2013 WL 4517825, at *3 (S.D. Ohio Aug. 26, 2013) (citing *Rauch v. Day & Night Mfg.*

Corp., 576 F.2d 697, 702 (6th Cir. 1978)). Federal Rule 8(a)(2) requires "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2); *see also Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). To meet this standard, a complaint must contain sufficient factual allegations to "state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). A complaint will not "suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement'" or "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements." *Id.* (quoting *Twombly*, 550 U.S. at 557).

Determining whether a complaint states a plausible claim for relief is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Ashcroft*, 556 U.S. at 679. When considering a motion to dismiss, a court must construe the complaint in the light most favorable to the plaintiff and accept all of the complaint's well-pleaded factual allegations as true. *Grindstaff v. Green*, 133 F.3d 416, 421 (6th Cir. 1998).

From Baxter's perspective, McIntire's punitive damages claim should be dismissed for three reasons. First, Baxter contends that the claim was not properly pleaded; the Complaint purportedly contains insufficient facts regarding Baxter's knowledge that the product was defective. (Baxter Mot. to Dismiss at 3–4 [ECF No. 16].) Second, Baxter argues that the claim is preempted by federal law. (*Id.* at 4–5.) And third, Baxter argues that punitive damages cannot be pleaded as a separate cause of action. (*Id.* at 5–6.) The Court begins with Baxter's second argument—federal preemption.

A. Federal Preemption

A discussion of Baxter's preemption argument requires, first, a review of the applicable law. This review starts with an Ohio statute.

Ohio Revised Code § 2307.80(A) permits the award of punitive damages against a manufacturer in a product liability claim. The permissibility of a punitive damages award is subject, however, "to divisions (C) and (D)" of the statute. O.R.C. § 2307.80(A). Division (C)(1)(a) precludes an award of punitive damages when the alleged device "was manufactured and labeled in relevant and material respects in accordance with the terms of an approval or license issued by the [FDA] under the 'Federal Food, Drug, and Cosmetic Act [FDCA].'" *Id.* § 2307.80(C)(1)(a). Division (C)(2), however, provides an exception to division (C)(1): "[d]ivision (C)(1) of this section does not apply" if the plaintiff can show by a preponderance of the evidence that "the manufacturer fraudulently and in violation of applicable regulations of the food and drug administration withheld from the food and drug administration information known to be material and relevant to the harm that the claimant allegedly suffered or misrepresented to the food and drug administration information of that type." *Id.* § 2307.80(C)(2).

Federal law adds an extra wrinkle to this state statutory scheme. The Supreme Court has held that state-law fraud-on-the FDA claims conflict with, and are, therefore, impliedly preempted by federal law. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348, 350–53 (2001). The Sixth Circuit has interpreted this implied preemption to mean that "state tort remedies requiring proof of fraud committed against the FDA are foreclosed." *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 966 (6th Cir. 2004). State-law claims "that the manufacturer misrepresented or withheld information about a drug from the FDA after the FDA had approved it" are also foreclosed. *Marsh v. Genentech, Inc.*, 693 F.3d 546, 551 (6th Cir. 2012) (citing *In re*

Aredia & Zometa Prods. Liab. Litig., 352 F. App'x 994, 995 (6th Cir. 2009)). These fraud-on-the-FDA claims are only permitted (i.e., not preempted) when the FDA itself has already found that the manufacturer committed the requisite fraud. *See id.* at 550 n.3, 551; *Garcia*, 385 F.3d at 966.

Applying these federal preemption principles to O.R.C. § 2307.80, this Court has concluded that a punitive damages claim is preempted if it relies on § 2307.80(C)(2) when the FDA itself has not already found that the manufacturer committed fraud. *See Thompson v. DePuy Orthopaedics, Inc.*, No. 1:13-cv-602, 2015 WL 7888387, at *18–19 (S.D. Ohio Dec. 4, 2015) (dismissing a punitive damages claim "to the extent it is based on Ohio Rev. Code § 2307.80(C)(2)"); *Monroe v. Novartis Pharm. Corp.*, 29 F. Supp. 3d 1115, 1130 (S.D. Ohio 2014) (dismissing a punitive damages claim because there had been no finding of fraud by the FDA); *Miller v. ALZA Corp.*, 759 F. Supp. 2d 929, 944–45 (S.D. Ohio 2010) ("Claims asserting fraud on the FDA are preempted by the [FDCA]."); *see also Decker v. GE Healthcare* (*In re Gadolinium-Based Contrast Agents Prods. Liab. Litig.*), Nos. 1:08 GD 50000 & 1:12 GD 50004, 2013 WL 587655, at *13–14 (N.D. Ohio Feb. 13, 2013) (dismissing the plaintiffs' punitive damages request because it was rooted in a fraud-on-the-FDA claim and there had been no finding of fraud by the FDA). Stated differently, when a punitive damages claim falls within the scope of division (C)(1) (of § 2307.80), a plaintiff will typically, to avoid that division's punitive damages bar, attempt to establish fraud on the FDA under division (C)(2). Due to federal preemption, though, a plaintiff can only avail himself of division (C)(2) if the FDA itself has already found the requisite fraud. *See Thompson*, 2015 WL 7888387, at *18–19; *Monroe*, 29 F. Supp. 3d at 1130.

As this Court has also held, however, there is no federal preemption when a plaintiff brings a punitive damages claim that does not fall within the scope of division (C)(1). *See Thompson v. DePuy Orthopaedics, Inc.*, No. 1:13-cv-602, 2014 WL 2874268, at *9 (S.D. Ohio June 24, 2014) ("While there is no question that DePuy received the requisite 510(k) approval for the bone cement, the facts alleged by Plaintiff are sufficient to show a plausible lack of compliance with the manufacturing and labeling requirements."); *Marcum v. DePuy Orthopedics, Inc.*, No. 1:12-cv-834, 2013 WL 1867010, at *6–7 (S.D. Ohio May 2, 2013) (permitting a punitive damages claim where the plaintiff alleged that the defendant's product was not actually manufactured in accordance with the terms of the relevant FDA approval).

The Court moves now to Baxter's preemption argument. Baxter argues that a punitive damages claim against a manufacturer in a product liability claim is preempted unless the FDA first makes a finding of fraud or misrepresentation. (Baxter Mot. to Dismiss at 4 [ECF No. 16].) Baxter asserts that here, because there are no allegations that the FDA has made a finding of fraud or misrepresentation as to Baxter, McIntire's punitive damages claim should be dismissed. (*Id.* at 5.)

McIntire, in response, argues that his punitive damages claim is not preempted by federal law because his claim does not fall within the scope of division (C)(1). (*See* McIntire Resp. at 6–8 [ECF No. 18].) The punitive damages claim, McIntire insists, derives from his allegation that the MiniCaps were not manufactured in accordance with the terms of an FDA approval or license. (*Id.*)

Although some of the allegations in McIntire's Complaint could be read as an attempt to invoke § 2307.80(C)(2) (i.e., argue a fraud-on-the FDA theory), (*see* Compl. ¶¶ 89–90 [ECF No. 1]), other allegations can be read as an assertion that Baxter's MiniCaps were not manufactured

in accordance with the terms of an FDA approval or license. (*See id.* ¶¶ 15, 65, 87.) And to the extent that McIntire's punitive damages claim hinges on the MiniCaps not being manufactured in accordance with the terms of an FDA approval or license, the claim falls outside the scope of § 2307.80(C)(1)(a) and is not preempted by federal law.

McIntire's allegations of manufacturing deviations save his punitive damages claim from preemption. He alleges that "[t]he MiniCap was approved via the [FDA's] 510(k) premarket approval process on January 29, 1990." (Compl. ¶ 15.) And he then alleges that "the MiniCaps sold to and utilized by [Mrs. McIntire] were defective in their manufacture in that the MiniCaps deviated in a material way from [Baxter's] designs and specifications and/or from other such typical said MiniCaps of the same product line." (*Id.* ¶ 65.) Viewed in the light most favorable to McIntire, these allegations are sufficient for the Court to plausibly infer that the MiniCaps that purportedly harmed Mrs. McIntire were not manufactured in accordance with the terms of an FDA approval or license.

B. Pleading Inadequacies

Baxter next moves to dismiss the punitive damages claim based on purported pleading inadequacies. The Complaint, Baxter argues, fails to sufficiently explain *how* Baxter knew the dangerous condition of the MiniCaps. (Baxter Mot. to Dismiss at 3 [ECF No. 16].)

In a product liability case, a manufacturer is liable for punitive damages if the plaintiff establishes, by clear and convincing evidence, that his harm was the result of "misconduct of the manufacturer . . . that manifested a flagrant disregard for the safety of persons who might be harmed by the product in question." O.R.C. § 2307.80(A).

McIntire has sufficiently pleaded a punitive damages claim. He alleges that

> [Baxter's] misconduct . . . constituted a conscious disregard for rights and safety to other persons, including [Mrs. McIntire], that had a great probability of causing

> substantial harm including, but not limited to, exposing Decedent and other users of the MiniCap to deadly disease and death from peritonitis, the serious potential danger of which was known to [Baxter] prior to [its] mailing of warning letters to users of the MiniCap.

(Compl. ¶ 88 [ECF No. 1].) And he further alleges:

> [P]rior to sending a voluntary recall letter to [Mrs. McIntire] on January 27, 2015, [Baxter] had become fully aware of the defects in the MiniCap product which caused [Mrs. McIntire's death] on January 18, 2015, yet [Baxter] maliciously concealed the defects in the MiniCap product from the FDA, consumers such as Decedent and other members of the public.
>
> [Baxter] maliciously failed and refused to warn [Mrs. McIntire] and other members of the public of the deadly dangers of their unwitting continued use of the defective MiniCap, in order to advance [Baxter's] pecuniary interests by avoiding a costly recall campaign, and/or replacement of defective products, and/or adverse publicity to [Baxter], and/or a decline in purchase by the public of the MiniCap product, and/or personal injury and/or wrongful death litigation by consumers injured or killed by the defective MiniCap product, all for the purposes of reducing the costs and maximizing the profits on the continued sales of the MiniCap product by [Baxter].

(*Id.* ¶¶ 89–90.)

The sufficiency of McIntire's punitive damages claim is bolstered by the language and timing of Baxter's warning letters and recall notice. (Compl. ¶¶ 19–21; Jan. 6, 2015 Ltr. at PageID 23–25 [ECF No. 1-3]; Jan. 12, 2015 Ltr. at PageID 26–28 [ECF No. 1-3]; Jan. 27, 2015 Recall Notice at PageID 31–32 [ECF No. 1-4].) The allegation that Baxter sent a letter to peritoneal dialysis providers on January 6—warning them of the increased risk of peritonitis posed by the defective MiniCaps—but waited until January 12 to warn peritoneal dialysis patients of that same risk, supports McIntire's allegations. And the additional delay between sending those letters on January 6 and 12 and recalling the defective MiniCaps on January 27 further support's McIntire's allegations. Viewing the allegations in the light most favorable to McIntire, these time lags indicate that Baxter delayed in warning peritoneal dialysis users of the MiniCap defects. The Court can plausibly infer that Baxter's inaction caused Mrs. McIntire's

harm and "manifested a flagrant disregard for the safety of persons who might be harmed by the product." *See* O.R.C. § 2307.80(A).[2]

Under Ohio law, McIntire has no obligation to plead *how* Baxter knew the dangerous condition of the MiniCaps. *See* O.R.C. § 2307.80(A). But if McIntire were subject to such a pleading requirement, his Complaint would have satisfied it. In Baxter's January 6, 2015 letter, which McIntire attaches to his Complaint, Baxter explains how it knew of the MiniCaps' dangerous condition:

> Baxter received complaints indicating that the sponge of the MiniCap was fully separated from the cap, partially protruding from the cap, or missing. . . .
>
> Use of MiniCaps with sponges fully separated or missing from the caps may compromise the ability of the MiniCap to provide a sterile barrier protection at the end of the transfer when the transfer set is not connected to the patient line of the automated peritoneal dialysis (APD) cassette or continuous ambulatory peritoneal dialysis (CAPD) twin bag set-ups. This may increase the risk of peritonitis.
>
> Use of MiniCaps with sponges partially protruding from the caps may encourage non-aseptic techniques, such as inadvertently touching the sponge to reposition it inside the cap. This may increase the risk of peritonitis.

(Jan. 6, 2015 Ltr. at PageID 23.) Baxter's insufficient pleading argument is not well taken.

C. Punitive Damages as a Separate Cause of Action

For its final argument, Baxter contends that McIntire's punitive damages claim should be dismissed because punitive damages cannot be pleaded as a separate cause of action. (Baxter Mot. to Dismiss at 5–6 [ECF No. 16].) McIntire, in response, insists that his punitive damages claim is not a true "stand-alone" cause of action, which would be impermissible under Ohio law. (McIntire Resp. at 8 [ECF No. 18].)

[2] Additionally, and as noted in the previous section, McIntire has sufficiently alleged that the MiniCaps in question were not manufactured in accordance with the terms of an FDA approval or license. (Compl. ¶¶ 15, 65, 87.)

Ohio does not allow a civil action maintained solely for punitive damages. *Graham v. Am. Cyanamid Co.*, Nos. C-2-94-423 & C-2-94-425, 2000 WL 1911431, at *12 (S.D. Ohio Dec. 21, 2000) (citing *Bishop v. Grdina*, 485 N.E.2d 704, 705 (Ohio 1985)). This is because punitive damages are a form of relief that derive from other causes of action. *See Raftery v. S. Lee Corp.*, No. 2:07-cv-649, 2007 WL 4085289, at *2 (S.D. Ohio Nov. 15, 2007); *Graham*, 2000 WL 1911431, at *12 ("[A] claim for punitive damages is derivative.") (citing *Moskovitz v. Mt. Sinai Med. Ctr.*, 635 N.E.2d 331, 342 (Ohio 1994)). A punitive damages claim stands alone—and is, thus, impermissible under Ohio law—if it is not derivative of some other cause of action that allows for punitive damages as relief. *Graham*, 2000 WL 1911431, at *12. Conversely, a request for punitive damages—even if listed as a separate cause of action in a complaint—is permitted under Ohio law if it is derivative of, or sufficiently tied to, another cause of action that allows for punitive damages as relief. *See, e.g.*, *Reber v. Lab. Corp. of Am.*, No. 2:14-cv-2694, 2015 WL 7076608, at *3–4 (S.D. Ohio Nov. 13, 2015) ("[B]ecause punitive damages are available in negligence actions under Ohio law, and because Plaintiff's complaint indicates that he seeks punitive damages for his negligence claims, the punitive-damages claim is not a stand-alone claim." (footnote omitted)); *Raftery*, 2007 WL 4085289, at *1–4.

This Court's decision in *Raftery v. S. Lee Corporation*, 2007 WL 4085289, at *1–4, is instructive. In *Raftery*, the plaintiffs pleaded a punitive damages claim as a separate count in their complaint. *Id.* at *1. Considering a motion to dismiss directed at that claim, the Court explained: "Although the punitive damages claim is a numbered count in the complaint, it is not a separate cause of action." *Id.* at *2. Because punitive damages "are awarded as an incident of the cause of action in which they are sought," the Court looked to the other claims within the complaint to determine if any would support a request for punitive damages. *Id.* Counts three and

four were tort claims for fraudulent misrepresentation and fraudulent inducement, respectively. *Id.* at *3. Both claims allowed for punitive damages as relief, and the Court, consequently, denied the motion to dismiss. *Id.* at *3–4.

McIntire's claim for punitive damages is not an impermissible, stand-alone cause of action. The punitive damages claim sufficiently derives from, and is tied to, at least two other causes of action that allow for punitive damages. (*See* Compl. ¶¶ 87–91 (requesting punitive damages based on Baxter's "misconduct, as previously outlined herein").) Specifically, punitive damages are available, by statute, as relief under McIntire's first and second causes of action, Strict Products Liability—Manufacturing Defect and Strict Products Liability—Defective Due to Inadequate Warning. *See* O.R.C. § 2307.80(A). And McIntire, as explained above, has pleaded sufficient factual allegations to pursue punitive damages under those claims.

III.

Baxter's Motion to Strike and Dismiss Plaintiff's Fifth Cause of Action for Punitive Damages [ECF No. 16] is, accordingly, **DENIED**.

IT IS SO ORDERED.

3-21-2017
DATE

EDMUND A. SARGUS, JR.
CHIEF UNITED STATES DISTRICT JUDGE